K031155

AUG 22 2003

510(k) Summary

Device Proprietary Name:	OsteoMed Subtalar Implant System
Device Common Name:	Subtalar Implant
Classification Name:	Screw, Fixation, Bone
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person:	Dawn T. Holdeman
Date Prepared:	April 7, 2003

Summary:

This submission describes the OsteoMed Subtalar Implant System indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion, but blocking excessive pronation and the resulting sequela. OsteoMed Subtalar Implants are intended for single use only.

The OsteoMed Subtalar Implant System is a spacer for stabilization of the subtalar joint made of Titanium Alloy. The OsteoMed Subtalar implants are offered in diameters of 6.0 to 12.0mm and in lengths of 10.0 to 15.0mm. Guide wires, cannulated screwdrivers and sizers will also be a part of the system.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Kinetikos Medical Subtalar MBA System (K960692).

Due to the similarity of materials and design to the predicate device, OsteoMed believes that the OsteoMed Subtalar Implant System does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

Ms. Dawn T. Holdeman
Regulatory Affairs and Document Control
OsteoMed L.P.
3885 Arapaho Road
Addison, Texas 75001

Re: K031155
Trade/Device Name: OsteoMed Subtalar Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 7, 2003
Received: May 28, 2003

Dear Ms. Holdeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OsteoMed "Indications for Use" Submission

510(k) Number: K031155

Device Name:	OsteoMed Subtalar Implant System
Indication for Use:	Indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. OsteoMed Subtalar Implants are intended for single use only.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 810.109)

Over-The Counter-Use _____ (Optical Format 1-)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031155